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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,254	10/13/2000	Harry M. Meade	GTC-43	9900

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/688,254	MEADE ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23,25,27-29,43 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23,25,27-29,43 and 44* is/are rejected.

7)☒ Claim(s) *44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 21-23, 25, 27-29, 43 and 44 are pending in the application.

This Office Action is in response to the Amendment filed on 12/18/06.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/06 has been entered.

Response to Amendment

Claims 21-23, 25, 27-29, 43 and 44 stand rejected under 35 U.S.C.103 (a) for reasons set forth below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-25, 27-30 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (5,981,714), in view of Radford et al. (5,955,270), Scharwz et al. (5,719,269), Wagner et al. (6,329,209), Meade et al. (5,750172), and Nuijens et al. (1997, JBC, Vol.272, No.13, pp.8802-8807). This rejection is re-written to address the claim amendment.

Cheng et al. teach a method of purifying a target polypeptide by using antibody which binds to a matrix. Cheng et al. also teach that the standard method for such purification consists preparation of antibody-matrix, binding an antigen to the antibody-matrix, removing

contaminants by washing, and elution of the antigen (see col. 7 line 56 through line 12, col. 8). However, Cheng et al. does not teach that the antibody is made transgenically. Cheng et al. do not teach that the target polypeptide is an antibody. Cheng et al. do not teach that the target polypeptide is a receptor. Cheng et al. do not teach that the antibody used to purify the polypeptide having either protein L or CBD.

Schwartz et al. teach that method of purifying an antibody by using immobilized ligand immobilized to a matrix is well known in the art (see col.1, 4th paragraph). Schwartz et al. also teach that bacterial protein A, G and L are commonly used in this method because they specifically bind to IgG antibodies (see col. 1 through col. 2, 2nd paragraph).

Radford et al. teach that by adding the cellulose binding domain to an expression construct makes it easier for the subsequent purification (col. 2 line 59 through col.3 lines 13). Radford et al. further teach a method of purifying cellobiohydrolase-1 comprising the cellulose-binding domain can be used to bind to a cellulose matrix and washing off other components, thereby purifying said enzyme.

Wagner et al. teach that a method of capturing proteins to an array chip by using capturing agents that are attached to the chip (col.3). Wagner et al. also teach that the capturing agents can bind a protein to itself in a specific manner. They include antibodies, wherein the binding partner is antigen, and receptors, wherein their binding partner is ligand (see col.4, lines 48-67).

Nuijens et al. teach the expression and characterization of the recombinant human lactoferrin secreted in milk of transgenic mice. Nuijens et al. teach that the transgenically

produced lactoferrin is very similar to the natural lactoferrin, and exerts same anti-bacterial and anti-inflammatory activities in vivo.

Meade et al. teach the production of a number of recombinant proteins including TPA, urokinase, growth hormones and immunoglobulins in the milk of transgenic non-human mammal (see col.3, 3rd paragraph, and Examples 1-3).

Based on the combination of teaching of Cheng et al. (5,981,714), Scharwz et al. (5,719,269), and Nuijens et al. (1997, JBC, Vol.272, No.13, pp.8802-8807), it would have been obvious to one of ordinary skill in the art to develop a method of purifying target polypeptide either from milk of a transgenic mammal or other mixtures by contacting the target polypeptide with a transgenically produced multivalent binding polypeptide, (for example, the antibody that is capable of binding to a matrix taught by Cheng et al.) having a first bindable eptitope which binds the target polypeptide (for example, the antigen taught by Cheng et al.) and a second bindable eptitope which binds a matrix, and subsequent elution of the polypeptide from the matrix. The ordinary artisan would have been motivated to do so because a transgenically produced polypeptide is structurally same as the natural occurring polypeptide as demonstrated by Nuijen et al. Further, Meade et al. teach the generation of recombinant immunoglobulins in the milk of the transgenic non-human mammal. Regardless whether the multivalent binding polypeptide is produced in the milk of the same transgenic mammal as the target polypeptide or in the milk in a second transgenic mammal, it can be used to purify the target polypeptide. The teaching of Cheng et al. do not specially indicate that the antibody needs to be separately purified before use. At the time of filing, the skill of art in producing recombinant protein in milk of transgenic mammal is high. Absent evidence to the contrary, one of ordinary skill in the art

would have reasonable expectation of success to develop such a purification method using the multivalent polypeptide that is produced by a transgenic mammal, either in the same transgenic mammal that produces the target polypeptide or in a different transgenic mammal. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill of art at the time the invention was made.

It would also have been obvious to one of ordinary skill of art to use CBD as the second binding moiety of the multivalent polypeptide based on the teaching of Cheng et al. (5,981,714), Scharwz et al. (5,719,269), Radford et al. (5,955,270), and Nuijens et al. (1997, JBC, Vol.272, No.13, pp.8802-8807). The ordinary artisan would have been motivated to do so because Radford et al. teach that CBD binds to cellulose matrix and makes it easier to purify proteins comprising this domain. Since the nucleic acid sequence encoding those binding domains are known, attaching them to a polypeptide would have been routine experimentation at the time of filing. Absent evidence from the contrary, the ordinary skill of art would have reasonable expectation of success to produce a multivalent polypeptide with CBD domain as second binding moiety transgenically and use it to purify a target polypeptide such as IgGs. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill of art at the time the invention was made.

It would also have been obvious to one of ordinary skill of art to use a receptor as the first binding moiety when the target polypeptide is a ligand or vice versa based on the teaching of Cheng et al. (5,981,714), Wagner et al. (6,329,209), and Nuijens et al. (1997, JBC, Vol.272, No.13, pp.8802-8807). One of ordinary skill of art would have been motivated to do so because Wagner et al. teach that receptor-ligand and antigen-antibody interaction is specific for protein

capturing agent to bind to the ligand in a biological sample. Many receptor and ligand have been cloned and characterized at the time of filing. One ordinary skill of art would have plenty of information to choose receptor when a ligand needs to be purified and vice versa. Absent evidence from the contrary, one of ordinary skill of art would have reasonable expectation to transgenically produce a multivalent polypeptide with a binding moiety from either a ligand or a receptor. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill of art at the time the invention was made.

Claim Objections

Claim 44 is objected to as being dependent upon a cancelled base claim (1). Applicant is advised to rewrite the claim in independent form including all of the limitations of (canceled) base claim (1).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER